

CHRISTEL BILLHOFER

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

07 CIV 9920

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CHRISTEL BILLHOFER, On Behalf of  
Herself and All Others Similarly Situated,

Plaintiff,

vs.

FLAMEL TECHNOLOGIES, SA, STEPHEN  
H. WILLARD, RAFAEL JORDA, KENNETH  
LUNDSTROM and RÉMI MEYRUEIX,

Defendants.

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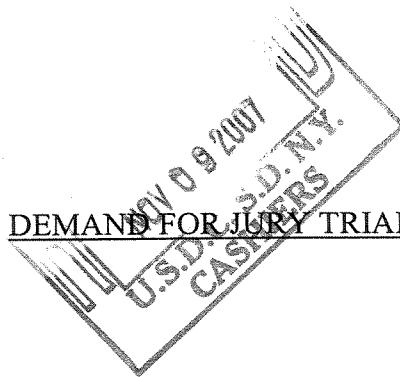
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Civil Action No.

COMPLAINT FOR VIOLATION OF THE  
FEDERAL SECURITIES LAWS

x

DEMAND FOR JURY TRIAL



## INTRODUCTION AND OVERVIEW

1. This is a class action for violations of the anti-fraud provisions of the federal securities laws on behalf of all purchasers of Flamel Technologies, SA (“Flamel” or “the Company”) American Depository Receipts (“ADR”) between March 23, 2007 and August 22, 2007 (the “Class Period”), who were damaged thereby (“the Class”).

2. Flamel, a biopharmaceutical company, develops polymer-based delivery technologies for medical applications. Its lead product is COREG CR for use in the treatment of moderate to severe congestive heart failure, left ventricular dysfunction following myocardial infarction and hypertension. The Company was founded in 1990 and is headquartered in Venissieux, France.

3. Throughout the Class Period, defendants made a series of false and misleading statements regarding the prospects for COREG CR.

4. On August 23, 2007, *Associated Press* published an article entitled “Flamel Technologies Shares Dive on Disappointing Coreg Study Results,” which stated in part:

Shares of Flamel Technologies plunged Thursday after a study of its once-daily heart disease drug failed to show any benefit over the twice-daily version.

The study results, published in the *Journal of Cardiac Failure*, showed that Coreg CR, which was launched March 22, was similarly effective as Coreg IR, the twice-daily version of the drug.

Shares of the Lyon, France-based biopharmaceutical company plunged \$3.12, or 24.6 percent, to close at \$9.56. The stock reached a 52-week low of \$8.96 during the regular trading session.

“As a result, we believe formulary adoption of Coreg CR will be hindered in the near-term, limiting potential growth of Coreg CR prescriptions,” said Merriman Curhan Ford analyst E. Russell McAllister.

5. On this news, Flamel’s ADR price dropped from \$12.68 to \$9.56 per share. This decrease in Flamel’s ADR price was a result of the artificial inflation caused by defendants’ misleading statements coming out of the ADR price.

6. Investors who purchased Flamel ADRs during the Class Period suffered damages, as they purchased the ADRs at artificially inflated prices. The ADRs declined rapidly once the study results, which defendants had known for several months, were disclosed.

#### **JURISDICTION AND VENUE**

7. The claims asserted arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (“1934 Act”) and Rule 10b-5 promulgated thereunder. Jurisdiction is conferred by §27 of the 1934 Act. Venue is proper pursuant to §27 of the 1934 Act. Flamel’s headquarters are located in Venissieux, France. The Company conducts business in this District and its ADRs trade on the NASDAQ, which is located in this District.

#### **THE PARTIES**

8. Plaintiff Christel Billhofer purchased Flamel ADRs during the Class Period as set forth in the attached certification and was damaged thereby.

9. Defendant Flamel’s headquarters are located in Venissieux, France. Flamel’s ADRs are traded under the symbol FLML on the NASDAQ, an efficient market.

10. Defendant Stephen H. Willard (“Willard”) was, at all relevant times, the Chief Executive Officer of Flamel.

11. Defendant Rafael Jorda (“Jorda”) was, at all relevant times, Chief Operating Officer, Executive Vice President and Director of Manufacturing and Development of Flamel.

12. Defendant Kenneth Lundstrom (“Lundstrom”) was, at all relevant times, Director of Research of Flamel.

13. Defendant Rémi Meyrueix (“Meyrueix”) was, at all relevant times, Scientific Director of Flamel.

## SCIENTER

14. During the Class Period, the defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made or acted in reckless disregard of the true information known to them at the time. In so doing, the defendants participated in a scheme to defraud and committed acts, practices and participated in a course of business that operated as a fraud or deceit on purchasers of Flamel ADRs during the Class Period.

### **FALSE AND MISLEADING STATEMENTS MADE DURING THE CLASS PERIOD**

15. On March 23, 2007, the Company issued a press release entitled "Flamel Technologies Welcomes Nationwide Availability of COREG CR™," which stated in part:

Flamel Technologies is pleased that GlaxoSmithKline yesterday announced the U.S. nationwide availability of COREG CR™ (carvedilol phosphate) extended release capsules for use in treating three cardiovascular conditions:

- High blood pressure, also known as hypertension;
- A heart attack that reduced how well the heart pumps (known medically as post-myocardial infarction left ventricular dysfunction); and
- Mild to severe heart failure.

COREG CR™ microparticles are produced by Flamel Technologies at its production facility in Pessac, France, using the company's MICROPUMP® technology platform.

Stephen H. Willard, Flamel's chief executive officer, stated "We are pleased that COREG CR™ will now be available to patients in the U.S. for the treatment of these three serious conditions. COREG CR™ is the first marketed product incorporating Flamel's MICROPUMP® technology. The success of the COREG CR™ program has generated considerable interest in our MICROPUMP® technology as well as in our MEDUSA® technology platform for the delivery of proteins and peptides. Interest in both technologies has never been higher."

16. On May 7, 2007, the Company issued a press release entitled "Flamel Technologies Announces First Quarter Results; COREG CR™ Launch; and Strong Sales of Product to GSK," which stated in part:

Flamel Technologies today announced its financial results for the first quarter of 2007.

Flamel's revenues during the quarter included the first royalties received from GlaxoSmithKline on sales of COREG CR, which was launched on March 22nd.

For the first quarter, Flamel reported total revenues of \$9.6 million versus \$5.1 million in the year-ago period. Product sales and services, consisting of COREG CR microparticle shipments to GSK, totaled \$5.4 million. Flamel's 2007 first quarter license and research revenues of \$3.1 million included a \$1 million milestone payment received from GSK; license and research revenues in the year-ago period were \$4.9 million and included \$2 million in milestones from GSK. Other revenues of \$1.1 million increased from \$0.2 million in the year-ago quarter and included royalties on the sale of COREG CR.

\* \* \*

Stephen H. Willard, Flamel's Chief Executive Officer, stated, "We are pleased with the early success of the COREG CR launch. Feedback from the cardiological community has been very positive. Physicians understand that the once-daily formulation of COREG CR offers key advantages to patients. It is well established that once-daily medications lead to greater patient compliance; non-compliance is one of the leading causes of hospitalization in heart failure patients. COREG CR delivers substantially the same peak and trough levels of carvedilol as the twice-a-day drug, taken as directed, but with a smoother release profile. Moreover, COREG CR has been observed to result in 24% fewer adverse events than immediate release Coreg in a crossover study conducted in hypertension patients. The success of COREG CR is generating positive interest in the Micropump platform from potential partners and interest in the Medusa® platform has also been renewed. We look forward to further positive developments with both platforms during 2007."

17. On May 15, 2007, the Company issued a press release entitled "Flamel Technologies Announces Results of Annual Meeting," which stated in part:

Flamel Technologies today announced the results of its annual meeting held on May 15, 2007.

\* \* \*

“We are pleased to have the strong support of our shareholders,” said Mr. Elie Vannier, non-Executive Chairman of Flamel. “Flamel is well positioned due to the success of COREG CR™, continued strong interest in the Company’s two technology platforms, Micropump® and Medusa®, and the innovations that our strong team of research scientists are making to build on both platforms.”

18. On August 1, 2007, the Company issued a press release entitled “Flamel Technologies Announces Second Quarter Results, New Medusa Relationships, and Ongoing Work on COREG CR®,” which stated in part:

Flamel Technologies today [announced] its financial results for the second quarter of 2007.

Flamel reported total revenues of \$7.4 million, compared to \$4.7 million in the second quarter of 2006. Product sales and services totaled \$4.8 million during the quarter. License and research revenues were \$1.8 million versus \$4.5 million in the year-ago period. Other revenues were \$0.8 million versus \$0.2 million in the year-ago period.

Costs and expenses during the second quarter were \$(21.5) million versus \$(14.3 million) in the year-ago period. Costs of goods and services sold in connection with the manufacture of COREG CR microparticles totaled \$(3.7) million versus \$(1.2) million in the second quarter of 2006. Research and development expenses were \$(13.2) million versus \$(9.0) million in the second quarter of 2006. SG&A was \$(4.6) million up from \$(4.1) million in the year-ago period.

Total costs and expenses less costs of goods and services sold (which are performed under a cost-plus contract with GSK) were \$(17.8) million versus \$(13.1) million in the year-ago quarter. Non-cash effects such as the unfavorable evolution of the dollar-euro exchange rate, as well as increased expenses relating to FAS-123R represented \$2.1 million of the difference between the two periods. The remainder related to increased expenses relating to pre-clinical and clinical trials.

Net loss in the second quarter of 2007 was \$(13.6) million, compared to a net loss of \$(9.5) million in the second quarter of last year. Net loss per share (basic) for the second quarter of 2007 was \$(0.57), compared to a net loss per share (basic) in the year-ago period of \$(0.40).

Cash and marketable securities at the end of the second quarter totaled \$47 million.

For the first half of 2007, Flamel reported total revenues of \$17.1 million versus \$9.8 million, in the first half of 2006. License and research revenues during the period were \$4.9 million versus \$9.4 million in the year-ago period. Product sales and services during the first six months of 2007 were \$10.2 million. Other revenues

during the first six months of 2007 were \$1.9 million versus \$0.4 million in the year-ago period.

During the first six months of 2007, total costs and expenses were \$(40.6) million versus \$(29.6) million in the first six months of 2006. Costs of goods and services sold relating to the manufacture of COREG CR microparticles totaled \$(8.2) million versus \$(3.1) million in the year-ago period. Research and development expenses during the first half of 2007 were \$(23.8) million versus \$(18.5) million during the year-ago period. Net of the effect of the dollar-euro exchange rate and increased stock-compensation expense associated with FAS 123-R, research and development costs increased by \$2.5 million during the period. SG&A totaled \$(8.7) million versus \$(8.0) million in the first six months of 2006. Net of the non-cash effects of the unfavorable exchange rate during the quarter, as well as increased costs associated with FAS-123R, SG&A during the period actually decreased by \$(0.3) million.

Net loss in the first half of 2007 was \$(22.7) million, compared to a net loss of \$(19.1) million in the first half of last year. Net loss per share (basic) for the first half of 2007 was \$(0.95), compared to net loss per share (basic) in the year-ago period of \$(0.80).

“Flamel has recently entered into further new relationships for its Medusa platform,” said Stephen Willard, Flamel’s Chief Executive Officer. “We believe that further potential agreements for other molecules are progressing well and that we are creating a diversified set of opportunities for our Medusa platform. The Phase I clinical trial on the new formulation of Basulin, our long-acting basal insulin, has commenced, and we continue to expect that it will be completed by the end of the third quarter. Regarding COREG CR, we believe it has strong ongoing potential in all indications. We continue to manufacture at the maximum rate and expect to do so even after the addition of new manufacturing capacity.”

19. The statements set forth above were materially false and misleading at the time they

were made because defendants were in possession of undisclosed clinical trial data showing that Coreg CR was no more effective than Coreg IR.

#### **THE TRUTH IS REVEALED**

20. On August 23, 2007, *Associated Press* published an article entitled “Flamel Technologies Shares Dive on Disappointing Coreg Study Results,” which stated in part:

Shares of Flamel Technologies plunged Thursday after a study of its once-daily heart disease drug failed to show any benefit over the twice-daily version.

\* \* \*

Shares of the Lyon, France-based biopharmaceutical company plunged \$3.12, or 24.6 percent, to close at \$9.56. The stock reached a 52-week low of \$8.96 during the regular trading session.

“As a result, we believe formulary adoption of Coreg CR will be hindered in the near-term, limiting potential growth of Coreg CR prescriptions,” said Merriman Curhan Ford analyst E. Russell McAllister.

21. As a result, the price of Flamel’s ADRs price dropped from \$12.68 to \$9.56 per share.

This decrease in the price of Flamel’s ADRs price was a result of the artificial inflation caused by defendants’ misleading statements coming out of the ADRs.

22. On August 24, 2007, *Motley Fool* reported the following in an article entitled “Flamel Under Fire”:

There’s no sector more volatile than the pharma sector as Flamel Technologies has proven in the past three months. Shares of the tiny drug developer have fallen 65% since the beginning of June and were down more yesterday after unfavorable data was released on its lead drug, heart failure treatment Coreg CR.

\* \* \*

Unfortunately for GSK and Flamel, the study showed that patients taking Coreg CR did not comply with usage regimens at a higher level than those taking the twice-a-day version. (This study was designed to be part of a one-two punch by GSK in conjunction with the ongoing COSMOS hypertension study, which is trying show that Coreg CR is superior to AstraZeneca’s Zestril.

One of the reasons Flamel and GSK ran the clinical trial that was written about yesterday was because previous studies had shown that up to 64% of hospitalizations related to heart failure were due to patient noncompliance with their medication. The obvious consequence of the unfavorable journal article is that Coreg CR may be slightly harder to market, and doctors may be more reluctant to prescribe it. This likely isn’t the major issue, though.

The problem with journal articles such as these is that they give ammunition to insurance companies to cover less of the drug’s costs or not pay for it at all. If insurers find the extra benefits of Coreg CR to be hazy, they will grant it less favorable coverage versus its generic immediate-release counterparts. This then means that insured patients would have to pay more out-of-pocket expenses if they want the convenience of a once-a-day pill, and also that GSK would be able to charge less of a premium for Coreg CR.

As Flamel has mentioned in the past, there are four areas of potential growth for the use of Coreg CR: patients switching from the IR version, using the drug in combination with other therapies, proving its broader use (a hypertension study is ongoing), and selling it internationally.

Investors shouldn't take this journal article to mean the end of Coreg CR's potential as a blockbuster (there's still the important COSMOS study, for example) but it's certainly bad news in near and intermediate terms until GSK puts out new positive data on the drug.

23. On August 27, 2007, *Motley Fool* reported the following in an article entitled "Flamel Falls Out of Compliance":

Well, *this* is a bitter pill for Flamel investors to swallow. A study released last week showed that the biotech's technology allowing once-a-day dosing of GlaxoSmithKline's Coreg CR is no better at encouraging compliance than the twice-a-day regimen patients followed with the original version of Coreg.

The market wallop the stock once again, cutting its value by nearly one-fourth last week. Flamel's stock is down 75% from its 52-week high.

Flamel investors had hoped that a commercial success from the application of its drug delivery technology to Glaxo's blockbuster beta-blocker Coreg would light a fire with other drug companies to sign on the dotted line. Sanofi-Aventis, for example, had captured about 30% of the market for its extended-release version for Ambien. In the past, Flamel has had deals with Biovail and Bristol-Myers Squibb, but the company's been glacially slow to seal new agreements.

Adding to the pessimism, Glaxo ran into problems with another of its drugs, Avandia, and turned its attention away from Coreg CR. It then reported that conversions to the new formulation weren't what it hoped, though it said it would be giving Coreg CR renewed focus in the weeks ahead. With generic versions of the original Coreg coming to market next month, Glaxo's window of opportunity to get patients onto its new CR program is quickly closing.

\* \* \*

The current study does crimp Flamel's hoped-for revenue streams from Coreg CR. Right now, the drug is the only approved product using Flamel's technology, and thus the only one providing royalty revenue. Flamel's management has said it's in discussions with as many as four new partners to license its technology. Should any one of them come through, new revenue spigots could open.

**LOSS CAUSATION/ECONOMIC LOSS**

24. During the Class Period, as detailed herein, defendants made false and misleading statements by means of concealment and obfuscation of critical clinical trial data and engaged in a scheme to deceive the market. This artificially inflated the price of Flamel's ADRs and operated as a fraud or deceit on the Class. Later, when defendants' prior misrepresentations and fraudulent conduct became apparent to the market, Flamel's ADRs fell precipitously, as the prior artificial inflation came out. As a result of their purchases of Flamel ADRs during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

**NO SAFE HARBOR**

25. Flamel's verbal "Safe Harbor" warnings accompanying its forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

26. The defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Flamel who knew that the FLS was false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made. On the contrary, such statements concealed critical data about the prospects of an important candidate drug.

**Applicability of Presumption of Reliance: Fraud on the Market**

27. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

- (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- (b) The omissions and misrepresentations were material;
- (c) The Company's ADRs traded in an efficient market;
- (d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's ADRs; and
- (e) Plaintiff and other members of the Class purchased Flamel ADRs between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

28. At all relevant times, the market for Flamel ADRs was efficient for the following reasons, among others:

- (a) As a regulated issuer, Flamel filed periodic public reports with the SEC; and
- (b) Flamel regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

**COUNT I**

**For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants**

29. Plaintiff incorporates ¶¶1-28 by reference.

30. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained

misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

31. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- (a) Employed devices, schemes, and artifices to defraud;
- (b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- (c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Flamel ADRs during the Class Period.

32. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Flamel ADRs. Plaintiff and the Class would not have purchased Flamel ADRs at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

33. As a direct and proximate result of defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Flamel ADRs during the Class Period.

## COUNT II

### **For Violation of §20(a) of the 1934 Act Against All Defendants**

- 34. Plaintiff incorporates ¶¶1-33 by reference.
- 35. The Individual Defendants acted as controlling persons of Flamel within the meaning of §20 of the 1934 Act. By virtue of their positions and their power to control public statements about Flamel, the Individual Defendants had the power and ability to control the actions of Flamel

and its employees. Flamel controlled the Individual Defendants and its other officers and employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

### **CLASS ACTION ALLEGATIONS**

36. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Flamel ADRs during the Class Period (the "Class"). Excluded from the Class are defendants, directors and officers of Flamel and their families and affiliates.

37. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Flamel had 23 million ADRs outstanding, owned by thousands of persons.

38. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) Whether the 1934 Act was violated by defendants;
- (b) Whether defendants omitted and/or misrepresented material facts;
- (c) Whether defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) Whether defendants knew or recklessly disregarded that their statements were false and misleading;
- (e) Whether the price of Flamel ADRs was artificially inflated; and
- (f) The extent of damage sustained by Class members and the appropriate measure of damages.

39. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

40. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

41. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

#### **PRAYER FOR RELIEF**

WHEREFORE, plaintiff prays for judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;
- B. Awarding plaintiff and the members of the Class damages and interest;
- C. Awarding plaintiff's reasonable costs, including attorneys' fees; and
- D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

#### **JURY DEMAND**

Plaintiff demands a trial by jury.

DATED: November 9, 2007

COUGHLIN STOIA GELLER  
RUDMAN & ROBBINS LLP  
SAMUEL H. RUDMAN  
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**CERTIFICATION OF NAMED PLAINTIFF  
PURSUANT TO FEDERAL SECURITIES LAWS**

CHRISTEL BILLHOFER ("Plaintiff") declares:

1. Plaintiff has reviewed a complaint and authorized its filing.
2. Plaintiff did not acquire the security that is the subject of this action at the direction of plaintiff's counsel or in order to participate in this private action or any other litigation under the federal securities laws.
3. Plaintiff is willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary.
4. Plaintiff has made the following transaction(s) during the Class Period in the securities that are the subject of this action:

**Acquisitions:**

Date Acquired	Number of Shares Acquired	Acquisition Price Per Share
4/24/07	400	29.60
4/24/07	500	29.60

**Sales:**

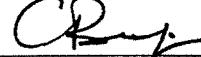
Date Sold	Number of Shares Sold	Selling Price Per Share

5. Plaintiff has not sought to serve or served as a representative party for a class in an action filed under the federal securities laws except as detailed below during the three years prior to the date of this Certification:

6. The Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond the Plaintiff's pro rata share of any recovery,

except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct.  
Executed this 1 day of Nov, 2007.

  
CHRISTEL BILLHOFER